(d) Additional animal facility requirements. In addition to those requirements given in §627.45, all animal facility external doors will be self-locking.

§627.47 Large-scale facilities.

The following requirements apply to facilities in which an individual culture of viable etiologic agents exceed 10 liters:

(a) *BL–1 LS.* In addition to the laboratory requirements stated §627.43(a), the exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (for example, incineration) to minimize the release of viable organisms.

(b) *BL–2 LS.* In addition to the requirements stated in §§627.44(a) and 627.47(a), these facilities will have—

(1) Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through equivalent treatment devices.

(2) A closed system used to propagate and grow viable organisms shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(3) Closed systems used for the propagation and growth of viable organisms shall be tested operationally for integrity of the containment features. The containment will be rechecked following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

(c) *BL–3 LS.* The requirements stated in §§627.45 and 627.57(b) apply, and all closed systems and other primary containment equipment used in handling cultures of viable organisms shall be located within a controlled area which meets the requirements of a BL–3 facility plus the following requirements:

(1) All utilities and service or process piping or wiring entering the controlled area shall be protected against contamination.

(2) A shower facility shall be provided. This facility shall be located near the controlled area.

(3) The controlled area shall be designed to preclude release of culture fluids outside in the event of an accidental spill or release from the closed systems or other primary containment equipment.

(4) The controlled area shall have a ventilation system capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure supply air, the system shall operate so as to prevent the reversal of air movement or shall be equipped with an alarm that would be actuated if reversal in the direction of air movement were to occur. The exhaust air from the controlled area shall not be recirculated to other areas of the facility. The exhaust air from the controlled area may be discharged to the outdoors after filtration or other means of effectively reducing an accidental aerosol burden, and dispersed clear of occupied buildings and air intakes.

§627.48 Toxins.

General requirements for all facilities in which toxins are used are as follows. Such facilities will—

(a) Have a ventilation system that provides three to six air changes per hour, and that provides a directional airflow inward relative to the access halls.

(b) Have a sink for handwashing.

(c) Have an eyewash available.

(d) Have bench tops that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(e) Have furniture, furnishings, and surfaces that are sturdy and designed to be easily cleaned.

(f) Be arranged so that items are accessible for cleaning.

(g) Have a quick-drench shower available within the facility.

(h) A fume hood, biological safety cabinet, glove box, or equivalent engineering control equipped with HEPA filters and with charcoal filters if volatile materials are being used.

Subpart H—Engineering Controls

§ 627.49 Introduction.

As required by the OSHA and recommended by the American Industrial Hygiene Association (AIHA) and the CDC, engineering controls and proper microbiological techniques are the primary means of protecting personnel who work with potentially hazardous biological materials. In situations of potentially higher hazard, these engineering controls are supplemented by personal protective clothing and equipment. Thus, the engineering controls discussed in this chapter will be the primary means of personnel and environmental protection when working with etiologic agents. Because of the importance of these engineering controls, this chapter contains not only requirements for the engineering and construction of these controls, but also requirements for their certification and continuous satisfactory performance. These will be described for each engineering control.

§ 627.50 Class I biological safety cabinet.

(a) *Description.* The Class I biological safety cabinet (figure H–I in appendix F to this part) is a ventilated cabinet for personnel protection only. The cabinet provides an uncirculated inward flow of air away from the operator. The exhaust is passed through a HEPA filter. It may be discharged into the laboratory or vented out of the laboratory and dispersed away from occupied spaces or air intakes. When the exhaust is recirculated in a BL–2 or BL–3 facility, the cabinet must be tested and certified annually. In a BL–4 facility, if the exhaust is recirculated, the cabinet must be tested and certified semiannually.

(b) *Uses.* These cabinets are used if personnel protection against the microorganisms is required; for modest quantities of volatile, toxic, or radioactive chemicals (in concentrations and quantities associated with biological systems) if vented to the outside; and when sterility is not required. They are commonly used for housing tabletop centrifuges, in the necropsy of small animals, and for changing animal bedding.

(c) *Prohibitions.* This class of cabinet is not to be used when sterility must be maintained. In addition, volatile, toxic, or radioactive materials can not be used in this class of cabinet when the exhaust air is not exhausted to the exterior.

(d) *Certifications and requirements.* (1) The inward air velocity on these cabinets will be an average of 100 plus or minus 20 linear feet per minute (lfpm). Each cabinet must be certified before use and semiannually thereafter by a face velocity test. Additionally, smoke tests will be performed annually to verify containment.

(2) The exhaust system will have a HEPA filter, which will be tested initially upon installation, after repair or replacement, and every 2 years thereafter (except when required more often). Filters will be certified to be 99.97 percent effective in capturing particulate matter by a leakage test using mineral oil or other appropriate aerosol dispersed as 0.3 micron droplets.

§ 627.51 Class II biological safety cabinet.

All Class II biological safety cabinets (figure H–II in appendix F to this part) are ventilated cabinets for personnel and product protection, having an open front with inward air flow for personnel protection.

(a) *Operating standards.* (1) All of these cabinets must conform and be certified to meet National Sanitation Foundation (NSF) Standard No. 49 revised, June 1987, for the applicable type of cabinet.

(2) After installation and before use, and annually thereafter, the cabinets will be tested in accordance with NSF Standard No. 49 (latest revision June 1987) as follows:

(i) Primary (required) tests—

(A) Velocity profile test.

(B) Work access opening airflow (face velocity) test.

(C) HEPA filter leak test.